Claims 10-12, 28-30, 38-39 were rejected under 35 U.S.C. § 103(a) as unpatentable over Cornelius in view of Andersen and further in view of Samson as applied to claims 3-5, 7-9, 14-15, 17, 22, 25-26, 32, 33, 35-37, 41, 42, 44, and 52 as above, and further in view of U.S. Patent No. 5,549,109 issued to Samson (hereinafter "Samson II").

**Rejections under 35 U.S.C. § 103**

The Examiner in an Advisory Action dated June 1, 2000 stated that the previously proposed amendments will not be entered because they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Applicants maintain that the obviousness rejection is improper and have amended independent claims 1, 24 and 31 to return them to their initially submitted form. New claims 54, 57, 58 and 60 are the same as previously cancelled claims 16, 23, 43 and 49, respectively, and new dependent claims 56 and 59 include the limitation of tightly knit interlocking loops.

To rely on a reference under 35 U.S.C. § 103, it must be analogous prior art. M.P.E.P § 2141.01(a). Applicants maintain that reliance on Andersen is improper because it is nonanalogous art. In order to rely on a reference as a basis for rejection, the reference must either be in the field of applicants' endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor is concerned. *In re Oetiker*, 997 F.2d 1443, 1446, 24 U.S.P.Q.2d 1443, 1445 (Fed.Cir. 1992). The Andersen device is a stent and the applicants' claims are to a catheter. A stent is not in the same field as applicants' invention nor is it pertinent to problems involving catheters.

A stent performs a function entirely different from a catheter. In particular, the Andersen stent is a knitted tubular member that is inserted into a body lumen. Metal and textile strands are knitted together to form the tube. The stent is radially compacted and then inserted into the body lumen where its allowed to expand. The metal strands are elastic and self-expanding and they structurally define the shape of the stent and maintain its shape when positioned. Once expanded, the textile strands contact the lumen wall to help induce blood clotting. The strands are loosely knit to enable easy expansion from a compressed state. A catheter, on the other hand, is a surgical instrument used to access remote regions of the body. A catheter cannot be substituted for a stent. Further, the catheter should not radially expand.

Patent Office classification of references is evidence of whether the art is analogous. M.P.E.P. §2141.01(a). Andersen is classified under U.S. Class 623 entitled "Prosthesis (i.e., artificial body members), parts thereof, or aids and accessories therefor." Catheters, like the one described in Cornelius, are in Class 604 entitled "Surgery." This difference in classification is evidence that Andersen is not analogous to art of the instant invention.

A person of ordinary skill in the art would not look to stents when solving problems associated with catheters because the problems associated with each, just like their functions, are different. For example, it is desirable to increase the "pushability" of a catheter through the body lumen. One would not look to stents to solve this and associated problems because a stent is designed to remain substantially in place in order to serve its function. A stent that is easily moved from position would result in constriction of the lumen area that was meant to be kept open by the stent, or would result in dislodging any clot that the stent helped to form. A person skilled in the art at the time the invention was made who was interested in solving problems associated with pushability and flexibility including kinking would not turn to an article that needs to remain substantially stationary to serve its purpose. Therefore, Andersen is non-analogous art that does not support an obviousness rejection in this case.

Obviousness cannot be established by combining or modifying the teachings of the prior art to produce the claimed invention, where there is no teaching, suggestion or motivation to do so found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir.1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). In order to produce the claimed invention, there has to be a teaching, suggestion or motivation in Cornelius and Andersen to combine or modify their teachings.

Regarding the radial expandability of the stent, there is no teaching, suggestion or motivation in the prior art to dismiss this feature as would be required to produce applicants' claimed invention. In fact, Andersen teaches away from using a non-expandable stent by disclosing the necessity of an expandable one. An expanded stent is sized to engage the wall of the body lumen and without compressibility it would be very difficult to move a fully expanded metal stent into position. Similarly, there is no teaching in Cornelius to modify the radially expandable knit of Andersen. It would not be obvious to one skilled in the art at the time the

invention was made to first modify the Andersen and then use it in a catheter to prevent kink formation.

Also, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). The proposed modification of using a non-expandable stent would render Andersen unsatisfactory for its intended purpose of moving a compressed stent into position and allowing it to expand. Also, modifying Cornelius to use an expandable stent would render it unsatisfactory for its intended purpose. Therefore, there is no suggestion or motivation to make the proposed modification.

Furthermore, Andersen teaches a knit having loosely interlocked loops so that it can easily be compressed and expanded. Andersen, col. 4, lines 57-61. Because Andersen teaches a knit that is loose, it teaches away from using a knit that will aid in kink resistance. In fact, modifying the Andersen knit into a tight knit would render Andersen unsatisfactory for its intended purpose of radial expandability. Also, the loose knit of Andersen would not impart Cornelius with the desired kink resistance of the instant invention and there is no teaching to modify the loose knit of Andersen.

Also, there is no teaching, modification or suggestion in Cornelius to substitute the knit for the braid. A knit and its advantages over a braid are nowhere mentioned in Cornelius and they are not obvious to one having ordinary skill in that art at the time the invention was made. The braid in Cornelius is located in the composite proximal section of the catheter and no braid is contemplated in the distal section, which is a polyethylene tube. Cornelius, col. 3, lines 50-60; col. 4, lines 31-36; col. 3, lines 25-34. Kinking in Cornelius is reduced by decreasing the relative flexibility of the distal and proximal sections and not by using a knit as in the instant invention. Cornelius, col. 4, lines 46-56. A knit of the instant invention provides significant advantages in kink resistance throughout the catheter sections and, in particular, in the distal section. A catheter with a knit is not taught or suggested in the prior art nor known to a person having ordinary skill in the art at the time the invention was made.

**New claim 55**

There is no disclosure, teaching or suggestion in the prior art to interpose the knit between the outer cover and the inner tubular liner such that the knit contacts the inner tubular

liner as in the instant invention. Newly added dependent claim 55 includes this limitation. In Cornelius, the braid is located in the outer tube 22 of the proximal section 40. Cornelius, col. 3, lines 25-28. Cornelius teaches away from locating the braid between the outer cover and inner liner by requiring an inflation lumen 26 to be defined between the inner wall of the outer tube 22 and the outer wall of inner tube 24. Cornelius, col. 3, lines 3-7. If Cornelius was modified to include a braid or knit located between the outer tube 22 and inner tube 24 in the manner of the instant invention, there would be no passage or inflation lumen to allow the inflation of the balloon 16, thereby, rendering Cornelius unsatisfactory for its intended purpose. Locating a braid or knit between the outer cover and inner tubular liner such that the knit contacts the inner tubular liner is not disclosed, suggested or taught by the prior art.

## SUMMARY

In summary, there has been no cogent reason given why a worker of ordinary skill in this art would combine the diverse teaching of the two references (Cornelius and Andersen). In view of this substantial gap in the necessary logic of a rejection under 35 U.S.C. §103, applicants have decided to revisit the earlier claim set and invite either an allowance on that basis or a final rejection so to accelerate the prosecution to the Board of Patent Appeals and Interferences.

However, in the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

Dated: August 21, 2000 By: _____

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